REMARKS/ARGUMENTS

The Present Invention and the Pending Claims

The present invention provides a method for selectively increasing glutamate and/or aspartate release in a central nervous system locus in a site-specific manner. Claims 1-6 currently are pending.

Summary of the Claim Amendments

Claim 1 has been amended to recite that the microstructure is non-spherical and comprises 1 - 90% thyrotropin-releasing hormone and the remainder a biodegradable matrix, as supported by the specification at, for example, page 6, line 13, through page 7, line 28. Claim 2 has been amended to delete text that is superfluous in view of amended claim 1. Claim 3 has been amended to be dependent on claim 1. Claims 5 and 6 have been added to further define the composition of the invention, as supported in the specification at page 7, lines 21 - 28. No new matter has been added by way of these amendments.

Information Disclosure Statement

The Office acknowledged receipt of the Information Disclosure Statement that was filed January 7, 2004, however copies of the non-patent literature documents, which were submitted in the parent application, could not be retrieved. As a result, the Office has not considered References AI-AU. Enclosed herewith are courtesy copies of the requested documents (i.e., copies of References AI-AU). Applicant hereby requests that the Examiner consider References AI-AU and return to Applicant an initialed PTO-1449 form.

Summary of the Office Action

The Office Action rejects claims 1-4 under 35 U.S.C. § 112 because the specification allegedly does not reasonably provide enablement for generically providing thyrotropin-releasing hormone (TRH) to the central nervous system. In addition, claim 1 is rejected under 35 U.S.C. § 103(a) as allegedly obvious over Tice et al. (U.S. Patent 5,360,610) in view of Heya et al. (EP 0 256 726 B1). Reconsideration of the pending claims is respectfully requested.

Discussion of the Enablement Rejection

Claims 1-4 allegedly are not enabled because the specification does not provide a method for generically delivering TRH to the central nervous system. Claim 1 has been amended to recite a method of delivering TRH to the central nervous system *via* at least one non-spherical microstructure comprised of 1-90% TRH and a biodegradable matrix, wherein the microstructure has a size and shape to prevent dispersion from the central nervous system locus. Dependent claims 5 and 6 further specify the microstructure as comprised of 1-60% or 1-10% TRH. The Examiner acknowledged the specification as enabling for a method for providing prolonged release of TRH by implanting the non-spherical microstructures comprising 1-90% TRH, preferably 1-60% TRH, and a biodegradable matrix, into the central nervous system. Hence, the amended claims are enabled, and this rejection should be withdrawn.

Discussion of the Obviousness Rejection

Claim 1 allegedly is obvious over Tice et al. in view of Heya et al. Tice et al. allegedly teaches a method of implanting microspheres directly into the central nervous system. The microspheres disclosed by Tice et al. are composed of biodegradable polymers and bioactive agents, including neurotransmitters, neuropeptides, and neurotrophic factors.

Claim 2 was not subject to the obviousness rejection in view of Tice et al. and Heya et al. Features of claim 2 have been added to claim 1. As a result, amended claim 1 is not obvious in view of the cited references, and this rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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